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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SAURO LIBERATORE, derivatively on behalf of PROVENTION BIO, INC., Plaintiff, vs. ASHLEIGH PALMER, ANDREW DRECHSLER, JEFFREY BLUESTONE, AVERY CATLIN, SEAN DOHERTY, JOHN JENKINS, WAYNE PISANO, and NANCY WYSENSKI, Defendants, and PROVENTION BIO, INC., Nominal Defendant.	**Case No.** 3:21-cv-14636 **DEMAND FOR JURY TRIAL**

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

INTRODUCTION

Plaintiff Sauro Liberatore ("Plaintiff"), by Plaintiff's undersigned attorneys, derivatively and on behalf of Nominal Defendant Provention Bio, Inc. ("Provention" or the "Company"), files this Verified Shareholder Derivative Complaint against Ashleigh Palmer, Andrew Drechsler, Jeffrey Bluestone, Avery Catlin, Sean Doherty, John Jenkins, Wayne Pisano, and Nancy Wysenski (collectively, the "Individual Defendants," and together with Provention, the "Defendants") for breaches of their fiduciary duties as directors and/or officers of Provention, unjust enrichment,

abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and for contribution under Sections 10(b) and 21D of the Exchange Act. As for Plaintiff's complaint against the Individual Defendants, Plaintiff alleges the following based upon personal knowledge as to Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls, and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Provention, legal filings, news reports, securities analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Provention's directors and/or officers from November 2, 2020 to April 8, 2021 (the "Relevant Period").

2. Provention is a New Jersey–based biopharmaceutical company dedicated to the interception and prevention of immune-mediated disease through the development of novel therapeutics. The Company's pipeline encompasses clinical-stage product candidates that have undergone clinical testing but may have been underdeveloped or deprioritized assets at other companies. The Company's lead candidate drug is PRV-031 ("teplizumab"), a monoclonal antibody being developed for the delay of clinical type 1 diabetes ("T1D") in at-risk individuals.

3. On May 9, 2018, Provention announced that it had entered into agreements with MacroGenics, Inc. ("MacroGenics"), a clinical-stage biopharmaceutical company, under which

the Company acquired all rights to teplizumab. MacroGenics had previously developed teplizumab under a 2007 partnership with Eli Lilly and Company ("Eli Lilly"), an American pharmaceutical company.

4. On June 9, 2019, the Company issued a press release entitled, "A Single Course of Provention's PRV-031 (Teplizumab) Delays Type 1 Diabetes Onset in High-Risk Individuals by at Least Two Years," announcing "that results from the National Institutes of Health (NIH)-sponsored 'At-Risk' Study" (the "TN-10 Study") had been published online. The press release described the TN-10 Study as an "[evaluation of] Provention's PRV-031 (teplizumab) for the prevention or delay of clinical T1D in relatives of type 1 diabetics at high-risk of developing the disease" which showed that "a single 14-day course of PRV-031 (teplizumab) significantly delayed the onset and diagnosis of clinical T1D, as compared to placebo, by a median of 2 years in children and adults considered to be at high risk." In this press release, Defendant Palmer touted the results from the TN-Study, stating:

> We are delighted with the results, which reinforce our confidence not only in PRV-031 (teplizumab), but in Provention's strategic intent to intercept and prevent immune-mediated disease. The ability to delay the onset of clinical T1D is an enormous breakthrough, given that a recent study indicated the life expectancy for patients diagnosed with T1D before the age of ten is reduced by as much as 16 years on average.
>
> Based on these results, we are evaluating a regulatory path forward for PRV-031 in at-risk individuals. We are also assessing PRV-031 in newly-diagnosed T1D patients in our Phase 3 PROTECT study, which commenced in April. Our broader goal for PRV-031 is to address the continuum of T1D and provide therapeutic options for this life-impacting and life-threatening autoimmune disease that, until now, has seen no disease-modifying innovation since the development of insulin a century ago.

5. On April 16, 2020, the Company issued a press release reporting the commencement of the rolling submission of the Biologics License Application ("BLA") to the U.S. Food and Drug Administration (the "FDA") for teplizumab, "an anti-CD3 monoclonal

antibody for the delay or prevention of clinical Type 1 Diabetes (T1D) in at-risk individuals, as indicated by the presence of two or more T1D-related autoantibodies." The press release further stated that "[r]olling submission allows for completed modules of the BLA to be submitted and reviewed by the FDA on an ongoing basis."

6. On November 2, 2020, the Company issued a press release reporting that the rolling submission of the BLA for teplizumab had been completed.

7. On January 4, 2021, the Company issued a press release announcing that the BLA for teplizumab had been filed by the FDA. The press release also stated that the FDA "granted Provention's request for Priority Review and assigned a user fee goal date of July 2, 2021, under the Prescription Drug User-Fee Act (PDUFA)."

8. On March 3, 2021, the Company issued a press release announcing the publication of extended follow-up data from the "pivotal 'At-Risk' TN-10 Study" and that "[r]esults show that a single 14-day infusion course of teplizumab (PRV-031) delayed the onset of clinical disease and insulin dependence in at-risk type 1 diabetes (T1D) patients by approximately three years (median of 32.5 months), adding one year to previously reported results."

9. On April 8, 2021, the Company issued a press release reporting that the Company had received, on April 2, 2021, a notification from the FDA in connection with the FDA's then-ongoing review of the BLA for teplizumab that it had "identified deficiencies that preclude discussion of labelling and post-marketing requirements/commitments at this time." The press release further reported that the FDA deemed the data and analysis submitted by the Company for its single, low-dose pharmacokinetic/pharmacodynamic ("PK/PD") bridging study (the "PK/PD Study") inadequate to conclude that the PK profiles of the two drug products evaluated in the study were comparable and that "additional data would be required before the FDA's considerations

could be satisfied."

10. On this news, Provention's share price dropped $1.73 (or 17.8%) to close at $8.00 on April 9, 2021.

11. During the Relevant Period, the Individual Defendants breached their fiduciary duties by personally making and/or causing the Company to make to the investing public a series of materially false and misleading statements and omissions of material fact regarding the Company's business, operations, and prospects. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements to the investing public that failed to disclose, *inter alia*, that: (1) the BLA for teplizumab contained deficiencies and inadequacies that would preclude FDA approval of the BLA in its submitted form; (2) the supporting evidence for the BLA for teplizumab was weak; (3) therefore the approval prospects of the BLA for teplizumab and teplizumab's commercialization timeline had been overstated; and (4) the Company failed to maintain internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

12. The Individual Defendants failed to correct and/or caused the Company to fail to correct these materially false and misleading statements and omissions of material fact, rendering them personally liable to the Company for breaching their fiduciary duties.

13. The Individual Defendants also breached their fiduciary duties by causing the Company to fail to maintain internal controls.

14. In addition, the Individual Defendants violated Section 14(a) of the Exchange Act by causing the Company to issue a proxy statement filed with the SEC on March 29, 2021 (the "2021 Proxy Statement") which contained false and misleading statements and omissions of material fact.

15. In light of the Individual Defendants' misconduct, which has subjected the Company, its Chief Executive Officer ("CEO"), and its Chief Financial Officer ("CFO") to a federal securities fraud class action lawsuit pending in the United States District Court for the District of New Jersey (the "Securities Class Action"); the need to undertake internal investigations; the need to implement adequate internal controls, the losses from the waste of corporate assets, the losses due to the unjust enrichment of the Individual Defendants who were improperly over-compensated by the Company and/or who benefited from the wrongdoing alleged herein, the Company will have to expend many millions of dollars.

16. In light of the breaches of fiduciary duty engaged in by the Individual Defendants, many of whom are the Company's current directors, their collective engagement in fraud, the substantial likelihood of the directors' liability in this derivative action and in the Securities Class Action, their being beholden to each other, their longstanding business and personal relationships with each other, and their not being disinterested and/or independent directors, a majority of Provention's Board of Directors (the "Board") cannot consider a demand to commence litigation against themselves on behalf of the Company with the requisite level of disinterestedness and independence.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act (15 U.S.C. § 78n(a)(1)), Rule 14a-9 of the Exchange Act (17 C.F.R. § 240.14a-9), and raise a federal question pertaining to the claims made in the Securities Class Action based on violations of the Exchange Act.

18. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant

to 28 U.S.C. § 1367(a).

19. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

20. The Court has personal jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District to justify the exercise of jurisdiction over them.

21. Venue is proper in this District because a substantial portion of the transactions and wrongs complained of herein occurred in this District. In addition, Defendants have conducted business in this District, and Defendants' actions have had an effect in this District.

PARTIES

Plaintiff

22. Plaintiff is a current shareholder of Provention common stock. Plaintiff has continuously held Provention common stock at all relevant times.

Nominal Defendant Provention

23. Provention is a Delaware corporation with its principal executive offices at 55 Broad Street, 2nd Floor, Red Bank, New Jersey 07701. Provention's shares trade on the NASDAQ under the ticker symbol "PRVB."

Defendant Palmer

24. Defendant Ashleigh Palmer ("Palmer") is a co-founder of Provention and has served as Provention's President and CEO and as a Company director since the Company's inception in 2016. According to the Company's 2021 Proxy Statement, as of March 15, 2021, Defendant Palmer beneficially owned 3,308,020 shares of the Company's common stock, which represented 5.2% of the Company's outstanding shares of common stock on that date. Given that

the price per share of the Company's common stock at the close of trading on March 15, 2021 was $13.73, Defendant Palmer owned approximately $45.4 million worth of Provention stock.

25. For the fiscal year ended December 31, 2020, Defendant Palmer received $2,007,936 in total compensation, including $595,000 in base salary, $267,750 in non-equity incentive plan compensation, $1,133,786 in option awards, and $11,400 in all other compensation.

26. The 2021 Proxy Statement said the following of Defendant Palmer, in relevant part:

> Mr. Palmer is a co-founder of Provention and has served as our President and Chief Executive Officer ("CEO") and on the board of directors since inception in 2016. Mr. Palmer currently serves as a non-executive director on the board of Third Pole, a clinical-stage biopharmaceutical company developing electric generated inhaled nitric oxide for certain life-threatening and debilitating critical care and chronic cardiopulmonary conditions, a role he has held from 2014 to 2020. Mr. Palmer is also President of Creative BioVentures™ Corp. (CBV), a strategic advisory firm serving the biopharma industry. Since founding CBV in 2002, Mr. Palmer has advised numerous clients regarding corporate positioning and strategy, fund raising, merger and acquisition transactions, clinical development and commercialization, and has undertaken a number of CEO and board level transformational leadership and turnaround assignments for both public and private biopharma companies. From 2015 through 2017, Mr. Palmer served as Executive Chairman of Celimmune, LLC, a clinical development-stage immunotherapy company dedicated to developing therapies for celiac disease and refractory celiac disease. Celimmune was acquired by Amgen Inc. in November 2017. Mr. Palmer served as Chief Executive Officer of Unigene Laboratories, Inc., a biopharmaceutical company, from 2010 to July 2013 in conjunction with a substantial restructuring of Unigene's debt. Following the debtholder's acquisition of substantially all of Unigene's assets, Unigene filed for bankruptcy in July 2013. Prior to founding Celimmune and CBV, Mr. Palmer was Vice President, Business Development for British Oxygen's Ohmeda Pharmaceutical Products, Inc., where he was instrumental in its sale to a consortium led by Baxter International Inc. by spinning out the company's inhaled nitric oxide assets as INO Therapeutics, Inc. (now Ikaria/Mallinckrodt). Under his leadership, as founding President and CEO, INO Therapeutics developed and commercialized the world's first selective pulmonary vasodilator, INOmax®, establishing a time-based pricing, orphan drug franchise, subsequently acquired by Mallinckrodt in 2015 for $2.3 billion. Earlier in his career, Mr. Palmer held positions of increasing responsibility in sales and marketing leadership at Reckitt Benckiser. Mr. Palmer received his MBA from the University of Bradford and his B.Sc. honors in Biochemistry and Applied Molecular Biology from the University of Manchester. Mr. Palmer's 30-plus years of extensive experience in the areas of corporate strategy formulation and preclinical and clinical drug evaluation, business and product development and

commercialization make him a valuable member of our board of directors.

Defendant Drechsler

27. Defendant Andrew Drechsler ("Drechsler") has served as Provention's CFO since September 2017. According to the Company's 2021 Proxy Statement, as of March 15, 2021, Defendant Drechsler beneficially owned 616,290 shares of the Company's common stock, which represented 1.0% of the Company's outstanding shares of common stock on that date. Given that the price per share of the Company's common stock at the close of trading on March 15, 2021 was $13.73, Defendant Drechsler owned approximately $8.5 million worth of Provention stock.

28. For the fiscal year ended December 31, 2020, Defendant Drechsler received $1,723,186 in total compensation, including $425,000 in base salary, $153,000 in non-equity incentive plan compensation, $1,133,786 in option awards, and $11,400 in all other compensation.

29. The 2021 Proxy Statement said the following of Defendant Drechsler, in relevant part:

> Mr. Drechsler joined Provention as Chief Financial Officer ("CFO") in September 2017. Mr. Drechsler has over 20 years of financial and operational leadership experience in life sciences companies. Prior to Provention, Mr. Drechsler was most recently CFO of Insmed Incorporated from 2012 to 2017. Mr. Drechsler's prior roles also include: CFO of VaxInnate Corporation, a privately held clinical-stage biotechnology company that developed vaccines for infectious diseases; CFO of publicly-traded Valera Pharmaceuticals where he completed an initial public offering; controller for Abbott Laboratories' Point of Care Division, which was publicly-traded as i-STAT Corporation prior to being acquired by Abbott; controller of Biomatrix, Inc., which was publicly-traded prior to being acquired by Genzyme. Mr. Drechsler currently serves on the board of directors of Baudax Bio, a position he has held since August 2020. Mr. Drechsler graduated magna cum laude from Villanova University with a BS in Accounting and received his certified public accountant license in New Jersey.

Defendant Bluestone

30. Defendant Jeffrey Bluestone ("Bluestone") has served as a Company director since March 2019. According to the 2021 Proxy Statement, as of March 15, 2021, Defendant Bluestone

beneficially owned 95,816 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on March 15, 2021 was $13.73, Defendant Bluestone owned approximately $1.3 million worth of Provention stock.

31. For the fiscal year ended December 31, 2020, Defendant Bluestone received $209,891 in total compensation, including $35,000 in fees earned or paid in cash and $174,891 in option awards.

32. The 2021 Proxy Statement said the following of Defendant Bluestone, in relevant part:

> Dr. Bluestone joined our board of directors in March 2019. Dr. Bluestone currently serves as the president and CEO of Sonoma Biotherapeutics, a role he has held since 2019. He has served as a member of the board of Gilead Sciences since 2019 and served on the board of Rheos Medicines in 2017. Dr. Bluestone has been the A.W. and Mary Margaret Clausen Distinguished Professor at University of California San Francisco (UCSF) in the Diabetes Center since 2000. From 2010 to 2015 Dr. Bluestone served as Executive Vice Chancellor and Provost at UCSF and from 2015 to 2019 as President and CEO of the Parker Institute for Cancer Immunotherapy. Dr. Bluestone was the founding director of the Immune Tolerance Network, the largest NIH-funded multicenter Exhibit A clinical immunology research program, testing novel immunotherapies in transplantation, autoimmunity and asthma/allergy. He was appointed by former Vice President, Joe Biden as a member of the Blue Ribbon Panel of scientific experts to guide the National Cancer Moonshot Initiative and also served as a senior investigator at the National Cancer Institute of the National Institutes of Health. Dr. Bluestone is a highly accomplished scientific researcher whose work over nearly three decades has focused on understanding the basic processes that control T-cell activation and immune tolerance in autoimmunity, organ transplantation and cancer. His research has led to the development and commercialization of multiple immunotherapies, including the first FDA-approved drug targeting T-cell co-stimulation to treat autoimmune disease and organ transplantation and the first CTLA-4 antagonist drugs approved by the FDA for the treatment of metastatic melanoma. Dr. Bluestone was part of the team of early developers of a novel anti-CD3 monoclonal antibody, now called teplizumab, a pro-tolerogenic drug that has shown clinical activity in type 1 diabetes (T1D), psoriatic arthritis, and the reversal of kidney transplant rejection. He received his B.S. and M.S. from Rutgers University and his Ph.D.in immunology from the Weill Cornell Graduate School of Medical Science. Dr. Bluestone's extensive scientific experience in autoimmunity and clinical development of FDA-approved therapies make him a valuable member of our board of directors.

Defendant Catlin

33. Defendant Avery Catlin ("Catlin") has served as a Company director since September 2018. According to the 2021 Proxy Statement, as of March 15, 2021, Defendant Catlin beneficially owned 124,613 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on March 15, 2021 was $13.73, Defendant Catlin owned approximately $1.7 million worth of Provention stock.

34. For the fiscal year ended December 31, 2020, Defendant Catlin received $230,891 in total compensation, including $56,000 in fees earned or paid in cash and $174,891 in option awards.

35. The 2021 Proxy Statement said the following of Defendant Catlin, in relevant part:

> Mr. Catlin joined our board of directors in September 2018. He currently serves on the Board of Corbus Pharmaceutical Holdings, Inc., a role he has held since August 2014. Mr. Catlin previously served as Senior Vice President and Chief Financial Officer of Celldex Therapeutics, Inc. from 2000 to 2017, where he raised more than $500 million from equity, convertible debt and private placement transactions, as well as devised and led financial strategies to successfully complete several asset acquisitions. Prior to Celldex, Mr. Catlin held senior financial and operational positions with public biopharma companies Endogen, Inc. and Repligen Corporation. Mr. Catlin earned a B.A. in Psychology from the University of Virginia and an MBA from Babson College. He is also a certified public accountant. Mr. Catlin's more than 22 years of experience as a senior financial officer of public biopharmaceutical companies make him a valuable member of our board of directors.

Defendant Doherty

36. Defendant Sean Doherty ("Doherty") has served as a Company director since September 2019. According to the 2021 Proxy Statement, as of March 15, 2021, Defendant Doherty beneficially owned 48,368 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on March 15, 2021 was $13.73, Defendant Doherty owned approximately $664,000 worth of Provention stock.

37. For the fiscal year ended December 31, 2020, Defendant Doherty received $219,506 in total compensation, including $44,615 in fees earned or paid in cash and $174,891 in option awards.

38. The 2021 Proxy Statement said the following of Defendant Doherty, in relevant part:

> Mr. Doherty joined our board of directors in September 2019. He serves as the Chairman of the JDRF T1D Fund, a venture philanthropy fund accelerating life-changing solutions to cure type 1 diabetes through catalytic commercial investments, since its inception in 2016. Since 2019, Mr. Doherty has served on the board of directors of IM Therapeutics, Inc. From 2005 to 2018, Mr. Doherty was a Managing Director and the General Counsel of Bain Capital, L.P., a private global investment firm. Previously, he was an attorney at Ropes & Gray LLP and an officer in the United States Navy. Mr. Doherty received his B.A. degree in Government from Harvard College and J.D. from Harvard Law School. Mr. Doherty's experience in the concept creation and continuing strategy management of the JDRF T1D Fund as well as his extensive philanthropic work in the T1D market environment make him a valuable member of our board of directors.

Defendant Jenkins

39. Defendant John Jenkins ("Jenkins") has served as a Company director since August 2020. According to the 2021 Proxy Statement, as of March 15, 2021, Defendant Jenkins beneficially owned 16,123 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on March 15, 2021 was $13.73, Defendant Jenkins owned approximately $221,000 worth of Provention stock.

40. For the fiscal year ended December 31, 2020, Defendant Jenkins received $1,079,956 in total compensation, including $14,542 in fees earned or paid in cash and $1,065,414 in option awards.

41. The 2021 Proxy Statement said the following of Defendant Jenkins, in relevant part:

> Dr. Jenkins joined our board of directors in August 2020. Dr. Jenkins served as the

Director of the Office of New Drugs (OND) at the United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) from 2002 to 2017, where he was responsible for more than 1,000 agency employees and 19 product-review divisions. During that time, he oversaw the review of thousands of new drug applications and biological licensing applications, as well as the approval of more than 400 new molecular entities. Dr. Jenkins served as a member of the CDER Senior Leadership Team and was involved in broad policy initiatives, including negotiation and implementation of the Prescription Drug User Fee and biosimilar programs. Dr. Jenkins began his FDA career in 1992 as a medical officer in the Division of Oncology and Pulmonary Drug Products. He subsequently served as Pulmonary Medical Group Leader and Acting Division Director before being appointed as Director of the Division of Pulmonary Drug Products in 1995. He then became the Director of the Office of Drug Evaluation II in 1999 and remained in that position until he was appointed Director of OND in 2002. Following his retirement from the FDA after over 25 years of federal service in January 2017, Dr. Jenkins joined Greenleaf Health, an FDA-focused, strategic consulting firm where he served as Principal, Drug and Biological Products. Dr. Jenkins is also a member of the board of Corbus Pharmaceuticals, where he has served since June 2018. Dr. Jenkins is board certified in internal medicine and pulmonary diseases by the American Board of Internal Medicine. He received his medical degree from the University of Tennessee, Memphis and completed his postgraduate medical training in internal medicine, pulmonary diseases, and critical care medicine at VA Commonwealth University/Medical College of VA. Prior to joining the FDA, Dr. Jenkins served as Assistant Professor of Pulmonary and Critical Care Medicine at VCU/MCV and as a Staff Physician at the Hunter Holmes McGuire VA Medical Center in Richmond, VA. Dr. Jenkins's significant expertise in the FDA review process and product candidate development make him a valuable member of our board of directors.

Defendant Pisano

42. Defendant Wayne Pisano ("Pisano") currently serves as Chairman of the Board and has served as a Company director since April 2018. According to the 2021 Proxy Statement, as of March 15, 2021, Defendant Pisano beneficially owned 112,113 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on March 15, 2021 was $13.73, Defendant Pisano owned approximately $1.5 million worth of Provention stock.

43. For the fiscal year ended December 31, 2020, Defendant Pisano received $261,949 in total compensation, including $87,058 in fees earned or paid in cash and $174,891 in option

awards.

44. The 2021 Proxy Statement said the following of Defendant Pisano, in relevant part:

> Mr. Pisano joined our board of directors in April 2018. He also serves on the board of biotechnology companies Oncolytics Biotech and Altimmune Inc., where he has been a director since May 2013 and September 2018, respectively. In addition, Mr. Pisano served on the board of directors of IMV, Inc., a biopharmaceutical company, from October 2011 to March 2021. Mr. Pisano served as President and CEO of VaxInnate, a biotechnology company, from January 2012 until November 2016. Prior to VaxInnate, Mr. Pisano was at Sanofi Pasteur from 1997 to 2011 and was President and CEO there from 2007 until his retirement in 2011. He has a bachelor's degree in biology from St. John Fisher College, New York and an MBA from the University of Dayton, Ohio. Mr. Pisano's depth of experience across the spectrum of commercial operations, public immunization policies and pipeline development make him a valuable member of our board of directors.

Defendant Wysenski

45. Defendant Nancy Wysenski ("Wysenski") has served as a Company director since May 2020. According to the 2021 Proxy Statement, as of March 15, 2021, Defendant Wysenski beneficially owned 16,123 shares of the Company's common stock. Given that the price per share of the Company's common stock at the close of trading on March 15, 2021 was $13.73, Defendant Wysenski owned approximately $221,000 worth of Provention stock.

46. For the fiscal year ended December 31, 2020, Defendant Wysenski received $1,305,976 in total compensation, including $32,000 in fees earned or paid in cash and $1,273,976 in option awards.

47. The 2021 Proxy Statement said the following of Defendant Wysenski, in relevant part:

> Ms. Wysenski joined our board of directors in May 2020. She served as the Executive Vice President and Chief Commercial Officer of Vertex Pharmaceuticals from December 2009 through her retirement in June 2012. During her tenure at Vertex, Ms. Wysenski was responsible for the launches of Incivek and Kalydeco. Prior to joining Vertex, Ms. Wysenski held the position of Chief Operating Officer of Endo Pharmaceuticals, a specialty pharmaceutical company, where she led sales, marketing, commercial operations, supply chain management, human resources

and various business development initiatives. Prior to her role at Endo, Ms. Wysenski participated in the establishment of EMD Pharmaceuticals, Inc., where she held various leadership positions, including the role of President and Chief Executive Officer from 2001 to 2006 and Vice President of Commercial from 1999 to 2001. From 1984 to1998, Ms. Wysenski held several sales focused roles at major pharmaceutical companies, including Vice President of Field Sales for Astra Merck, Inc. Ms. Wysenski has served as a member of the board of directors of Alkermes plc and Cytokinetics Inc. since 2013 and 2020, respectively. Ms. Wysenski formerly served as a director on the board of Tetraphase Pharmaceuticals Inc. from 2014 to 2020, Dova Pharmaceuticals, Inc. from 2018 to 2019 and Inovio Pharmaceuticals, Inc. from 2015 to 2017. She is a founder of the Research Triangle Park chapter of the Healthcare Businesswomen's Association and served on the Nominating Committee and National Advisory Board of the Healthcare Businesswomen's Association. Ms. Wysenski's expertise in the commercial launch of multiple products and her previous commercial leadership experience make her a valuable member of our board of directors.

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

48. By reason of their positions as officers, directors, and/or fiduciaries of Provention and because of their ability to control the business and corporate affairs of Provention, the Individual Defendants owed Provention and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Provention in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Provention and its shareholders so as to benefit all shareholders equally.

49. Each director and officer of the Company owes to Provention and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligations of fair dealing.

50. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Provention, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

51. To discharge their duties, the officers and directors of Provention were required to

exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

52. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Provention, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also officers and directors of the Company has been ratified by the remaining Individual Defendants who collectively comprised the Company's Board at all relevant times.

53. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful and accurate information.

54. To discharge their duties, the officers and directors of Provention were required to

exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Provention were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware, New Jersey, and the United States, and pursuant to Provention's own Code of Business Conduct and Ethics ("Code of Conduct");

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) remain informed as to how Provention conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Provention and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Provention's operations would comply with all applicable laws and Provention's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(f) exercise reasonable control and supervision over the public statements

made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

55. Each of the Individual Defendants further owed to Provention and the shareholders the duty of loyalty requiring that each favor Provention's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence or knowledge of the affairs of the Company to gain personal advantage.

56. At all times relevant hereto, the Individual Defendants were the agents of each other and of Provention and were at all times acting within the course and scope of such agency.

57. Because of their advisory, executive, managerial, and directorial positions with Provention, each of the Individual Defendants had access to adverse, non-public information about the Company.

58. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Provention.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

59. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants

caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

60. The purpose and effect of the conspiracy, common enterprise, and common course of conduct was, among other things, to (i) facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, gross mismanagement, abuse of control, and violations of the Exchange Act; (ii) conceal adverse information concerning the Company's operations, financial condition, legal compliance, future business prospects and internal controls; and (iii) to artificially inflate the Company's stock price.

61. The Individual Defendants accomplished their conspiracy, common enterprise, and common course of conduct by causing the Company purposefully or recklessly to conceal material facts, fail to correct such misrepresentations, and violate applicable laws. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants who is a director of Provention was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

62. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in, or substantially assisted in the accomplishment of that wrongdoing, and was or should have been aware of his or her overall contribution to and furtherance of the wrongdoing.

63. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Provention, and was at all times acting within the course and scope of such agency.

PROVENTION'S CODE OF CONDUCT AND AUDIT COMMITTEE CHARTER

64. The Company's Code of Conduct states that Provention's general policy is "to conduct its business activities and transactions with the highest level of integrity and ethical standards and in accordance with all applicable laws." Furthermore, "[r]eferences in this Code to employees are intended to cover all employees, including officers and, as applicable, directors."

65. Under the section, "Compliance with Laws, Rules and Regulations," the Code of Conduct instructs, in relevant part:

> It is the personal responsibility of each employee, officer and director to adhere to the [sic] both the spirit and the form of the standards and restrictions imposed by those laws, rules and regulations in the performance of their duties for the Company, including those relating to accounting and auditing matters and insider trading.

66. Under the section, "Fair Dealing," the Code of Conduct states, in relevant part: "No director, officer or employee should take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts, or any other unfair business practice."

67. Under the section, "Protection and Proper Use of Company Assets," the Code of Conduct states, in relevant part, that "[a]ll directors, officers and employees should protect the Company's assets and ensure their efficient use."

68. Under the section, "Disclosure," the Code of Conduct states, in relevant part:

> Each director, officer, and employee, to the extent involved in the Company's disclosure process, must: (a) be familiar with and comply with the Company's disclosure controls and procedures and its internal control over financial reporting, to the extent relevant to his or her area of responsibility, so that the Company's public reports and documents filed with the SEC comply in all material respects

> with the applicable federal securities laws and SEC rules; and (b) to the extent appropriate within his or her area of responsibility, take all necessary steps to ensure that all filings with the SEC and all other public communications about the financial and business condition of the Company provide full, fair, accurate, timely and understandable disclosure.

Furthermore, each director, officer, or employee must "not knowingly misrepresent, or cause others to misrepresent, facts about the Company to others, whether within or outside the Company, including to the Company's independent auditors, governmental regulators and self-regulatory organizations."

69. Under the section, "Honest and Ethical Conduct," the Code of Conduct states that "[i]t is the policy of the Company to promote high standards of integrity by conducting our affairs in an honest and ethical manner."

70. Under the section, "Legal Compliance," the Code of Conduct states that "[o]beying the law, both in letter and in spirit, is the foundation of this Code. Our success depends upon each employee's operating within legal guidelines and cooperating with local, national and international authorities."

71. The "Legal Compliance" section of the Code of Conduct goes on to state: "[w]e expect employees to understand the legal and regulatory requirements applicable to their business units and areas of responsibility and to comply with the relevant laws, rules and regulations associated with their employment, including laws prohibiting insider trading[.]"

72. Under the section, "Research and Development; Regulatory Compliance," the Code of Conduct states: "[t]he research and development of our products is subject to a number of legal and regulatory requirements, including standards related to ethical research procedures and proper scientific conduct. We expect employees to comply with all such requirements."

73. Under the section, "Accuracy of Books and Records and Financial Reporting," the

Code of Conduct instructs the following:

> The integrity of our records and public disclosure depends upon the validity, accuracy and completeness of the information supporting the entries to our books of account. Therefore, our corporate and business records should be completed accurately and honestly. The making of false or misleading entries is strictly prohibited. Our records serve as a basis for managing our business and are important in meeting our obligations to customers, suppliers, creditors, employees and others with whom we do business. As a result, it is important that our books, records and accounts accurately and fairly reflect, in reasonable detail, our assets, liabilities, revenues, costs and expenses, as well as all transactions and changes in assets and liabilities. We require that:
>
> 1. no entry be made in our books and records that intentionally hides or disguises the nature of any transaction or of any of our liabilities, or misclassifies any transactions as to accounts or accounting periods;
>
> 2. transactions be supported by appropriate documentation;
>
> 3. the terms of commercial transactions be reflected accurately in the documentation for those transactions and all such documentation be reflected accurately in our books and records;
>
> 4. employees comply with our system of internal controls; and
>
> 5. no cash or other assets be maintained for any purpose in any unrecorded or "off-the-books" fund.
>
> Employees who are responsible for accounting matters or contribute to or prepare the Company's financial statements, periodic reports filed with the Securities and Exchange Commission (the "SEC") or other public disclosure documents or communications should ensure that our books, records and accounts are accurately maintained, be familiar with our disclosure controls and procedures and internal controls and take all necessary steps to ensure that all reports filed with or submitted to the SEC and all other public disclosure regarding our business provide full, fair, accurate, timely and understandable disclosure and fairly present our financial condition and results of operations. All employees are expected to cooperate fully with our independent auditors and persons performing an internal audit function.

74. Under the section, "Protection and Proper Use of Company Assets," the Code of Conduct instructs the following, in relevant part: "All employees are expected to protect our assets and ensure their efficient use. Theft, carelessness and waste have a direct impact on our financial condition and results of operations."

75. The Company's Audit Committee Charter also entrusts the Individual Defendants on the Audit Committee with additional responsibilities. The Audit Committee Charter states, in relevant part:

> **PURPOSE**
>
> The purpose of the Audit Committee (the "Committee") is to assist the Board of Directors (the "Board") of Provention Bio, Inc. (the "Company") in fulfilling its responsibility to oversee (a) the integrity of the Company's financial statements, the Company's accounting and financial reporting processes and financial statement audits, (b) the Company's compliance with legal and regulatory requirements, (c) the Company's systems of internal control over financial reporting and disclosure controls and procedures, (d) the independent auditor's engagement, qualifications, performance, compensation and independence, (e) review and approval of related party transactions in accordance with the Policies and Procedures for Related Party Transactions, (f) compliance with the Company's Code of Business Conduct and Ethics and the Audit Committee Procedures for Reporting Potential Wrongdoing and (g) the communication among the Company's independent auditors, the Company's financial and senior management and the Board.
>
> In order to serve these functions, the Committee will have unrestricted access to Company personnel and documents, and will have the authority to direct and supervise an investigation into any matters within the scope of its duties.
>
> * * *
>
> **RESPONSIBILITIES**
>
> Within the scope of the role of the Committee described above, the Committee is charged by the Board with the responsibility to:
>
> 1. Appoint, (and recommend that the Board submit for stockholder ratification, if applicable), compensate, retain and oversee the work performed by the independent auditor retained for the purpose of preparing or issuing an audit report or performing other audit or audit-related services. The Committee will review the performance and independence of the independent auditor and remove the independent auditor, if circumstances warrant. The independent auditor shall report directly to the Committee and the Committee will oversee the resolution of any disagreements between management and the independent auditor, if any disagreements arise.
>
> 2. The Committee must pre-approve all audit, review, and non-audit services (including any internal control-related services) to be provided to the

Company or its subsidiaries by the independent auditor. The Committee may establish pre-approval policies and procedures in compliance with applicable SEC rules.

3. Obtain and review at least annually a formal written report from the independent auditor delineating: (a) the auditor's internal quality-control procedures; (b) any material issues raised by the most recent internal quality-control review, peer review or Public Company Accounting Oversight Board review of the auditor, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by the auditor, and any steps taken to deal with any such issues; and (c) all relationships between the independent auditor and the Company or any of its subsidiaries, in order to assess the auditor's objectivity and independence. After reviewing the foregoing report and the independent auditor's work throughout the year, the Committee shall evaluate the independent auditor's qualifications, performance and independence. This evaluation shall include the review and evaluation of the lead partner of the independent auditor. In making its evaluation, the audit committee shall take into account the opinions of management and, if applicable, the Company's internal auditors (or other personnel responsible for the internal audit function). In addition to assuring the regular rotation of the audit partners on the engagement team as required by law, the Committee shall consider whether, in order to assure continuing auditor independence, there should be regular rotation of the audit firm itself. The Committee shall present its conclusions with respect to the independent auditor to the Board. Upon receipt of such written report, the Committee shall discuss with the independent auditor any such disclosed relationships and their impact on the independent auditor's objectivity and independence, and take appropriate actions to oversee the independence of the independent auditor.

4. Discuss with the independent auditors the matters required in accordance with the applicable requirements of the Public Company Accounting Oversight Board Auditing Standards No. 1301, Communications with Audit Committees, including such matters as: the quality and acceptability of the accounting principles applied in the financial statements; new or changed accounting policies, the effect of regulatory and accounting initiatives, and significant estimates, judgments, uncertainties or unusual transactions; the selection, application and effects of critical accounting policies and estimates applied by management; issues raised by any "management" or "internal control" letter from the auditors, problems or difficulties encountered in the audit and management's response to such problems or difficulties, significant disagreements with management or other significant aspects of the audit; and any off-balance sheet transactions, and relationships with any unconsolidated entities or any other persons, which may have a material current or future effect on the financial condition or

results of operations of the Company and are required to be reported under SEC rules.

5. Discuss with the independent auditors the Committee's understanding of the Company's relationships and transactions with related parties that are significant to the Company; and to review and discuss with the Company's independent auditors the auditors' evaluation of the Company's identification of, accounting for, and disclosure of its relationships and transactions with related parties, including any significant matters arising from the audit regarding the Company's relationships and transactions with related parties.

6. Set policies for the hiring of employees or former employees of the Company's independent auditor.

7. Review management's report on internal controls and the independent auditor's attestation of management's report, when and as required by Section 404 of the Sarbanes-Oxley Act of 2002, and discuss with management and the independent auditors (a) any significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information and (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

8. Review and discuss with management and the independent auditor, prior to release to the general public and legal and regulatory agencies, the annual audited financial statements and quarterly financial statements, including disclosures contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations," and matters required to be reviewed under applicable legal, regulatory or NASDAQ listing rule requirements, including without limitation critical accounting policies and practices.

9. Discuss with management and the independent auditor, as appropriate, prior to release to the general public and legal and regulatory agencies, earnings press releases and financial information and, if applicable, earnings guidance.

10. Discuss with management and the independent auditors all critical accounting policies and practices to be used in the audit; all alternative treatments within generally accepted accounting principles for policies and practices relating to material items, including the ramifications of the use of such alternative disclosures and treatments and the treatment preferred by the independent auditors; and other material written or other

communications between independent auditor and management, such as any management letter or schedule of unadjusted differences.

11. Recommend to the Board whether the financial statements should be included in the Company's Annual Report on Form 10-K.

12. Discuss guidelines and policies developed by Company management and the Board with respect to risk assessment and risk management and the steps that the Company's management has taken to monitor and control financial risk exposure, including anti-fraud programs and controls.

13. Conduct any activities relating to the Company's Code of Business Conduct and Ethics as may be delegated from time to time to the Committee by the Board.

14. Review and investigate any matters pertaining to the integrity of management, including conflicts of interest, or adherence to standards of business conduct as required in the policies of the Company.

15. Review and approve related party transactions according to such policies as may be adopted by the Board or a committee thereof from time to time.

16. Meet, as frequently as it deems appropriate, separately with (a) the Chief Executive Officer, Principal Financial Officer and other members of senior management, (b) internal auditors (or other personnel responsible for the internal audit function), if applicable, and (c) the independent auditors, in each case to discuss any matters that the Committee or such persons believe should be discussed privately.

17. Establish procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters, including procedures for the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting, auditing matters or violations of the Company's Code of Business Conduct and Ethics.

18. Prepare an audit committee report in accordance with SEC regulations to be included in the Company's annual proxy statement to the extent applicable.

19. At least annually, evaluate the performance of the Committee, review and reassess this charter and, if appropriate, recommend changes to the Board.

20. Perform such other duties and responsibilities as may be assigned to the Committee by the Board.

76. In violation of the Code of Conduct and the Company's corporate governance documents, the Individual Defendants conducted little, if any, oversight of the Company's engagement in the Individual Defendants' scheme to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of the Exchange Act, and aiding and abetting thereof. Also in violation of the Code of Conduct, the Individual Defendants failed to maintain the accuracy of Company records and reports, comply with applicable laws and regulations, including "standards related to ethical research procedures and proper scientific conduct," and conduct affairs in an honest and ethical manner. In violation of the Audit Committee Charter, the Individual Defendants on the Audit Committee failed to fulfill their responsibilities in overseeing, *inter alia*, the Company's compliance with legal and regulatory requirements and the Company's systems of internal control.

INDIVIDUAL DEFENDANTS' MISCONDUCT

Background

77. Provention is a New Jersey–based biopharmaceutical company focused on intercepting and preventing immune-mediated disease through the development of novel therapeutics. The Company's pipeline features clinical-stage product candidates that have undergone clinical testing. The Company's lead candidate drug is teplizumab, an anti-CD3 monoclonal antibody being developed for the delay of clinical T1D in at-risk individuals.

78. The Company acquired teplizumab from MacroGenics in May 2018. Contrary to the Company's focus on evaluating whether teplizumab could delay or prevent the onset of T1D in pre-symptomatic patients, Macrogenics' research on teplizumab focused on evaluating whether teplizumab could be used to treat patients with recent-onset T1D.

79. On July 19, 2018, Provention closed its IPO at a price of $4.00 per share, generating gross proceeds of $63.9 million.

80. On June 9, 2019, the Company issued a press release announcing that results from the NIH-sponsored TN-10 Study had been published online. The press release described the TN-10 Study as an "[evaluation of] Provention's PRV-031 (teplizumab) for the prevention or delay of clinical T1D in relatives of type 1 diabetics at high-risk of developing the disease" which showed that "a single 14-day course of PRV-031 (teplizumab) significantly delayed the onset and diagnosis of clinical T1D, as compared to placebo, by a median of 2 years in children and adults considered to be at high risk." In this press release, Defendant Palmer touted the results from the TN-Study, stating:

> We are delighted with the results, which reinforce our confidence not only in PRV-031 (teplizumab), but in Provention's strategic intent to intercept and prevent immune-mediated disease. The ability to delay the onset of clinical T1D is an enormous breakthrough, given that a recent study indicated the life expectancy for patients diagnosed with T1D before the age of ten is reduced by as much as 16 years on average . . . . Based on these results, we are evaluating a regulatory path forward for PRV-031 in at-risk individuals. We are also assessing PRV-031 in newly-diagnosed T1D patients in our Phase 3 PROTECT study, which commenced in April. Our broader goal for PRV-031 is to address the continuum of T1D and provide therapeutic options for this life-impacting and life-threatening autoimmune disease that, until now, has seen no disease-modifying innovation since the development of insulin a century ago.

81. On April 16, 2020, the Company issued a press release reporting its initiation of the rolling submission of the BLA for teplizumab to the FDA. In this press release, Defendant Palmer stated that "[t]he initiation of our BLA submission process represents an important milestone for Provention as we advance teplizumab toward the market as the first-ever treatment for patients at-risk of advancing to clinical type 1 diabetes." He continued by saying:

> The data from the [TN-10 Study], published last year, underscores the transformative therapeutic potential of teplizumab to delay or prevent the onset of clinical-stage, insulin-dependent, T1D. We remain on track to complete the BLA

> submission by year-end and look forward to working with the FDA as we advance the regulatory process.

False and Misleading Statements

November 2, 2020 Press Release

82. On November 2, 2020, the Company issued a press release announcing the completion of the rolling submission of the BLA for teplizumab to the FDA for "the delay or prevention of clinical type one diabetes (T1D) in at-risk individuals with the submission of the chemistry, manufacturing and controls (CMC) and administrative information modules." The press release also stated:

> In August 2019, teplizumab was granted Breakthrough Therapy Designation (BTD) by the FDA. As afforded by the BTD, Provention has expressly requested a Priority Review in conjunction with the completion of the final submission. A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review). If approved by FDA, ***Teplizumab has the potential to be the first disease-modifying therapy for T1D***.

(Emphasis added.)

83. The November 2, 2020 press release also quoted Defendant Palmer:

> Our submission of the final modules of the rolling BLA represents a significant milestone for Provention Bio and a critical step toward the potential first major advancement in T1D therapeutics since insulin was introduced a century ago . . . . We look forward to continuing on our path toward changing the current treatment paradigm for T1D and, if approved, bringing teplizumab, designated by the FDA as a Breakthrough Therapy, to the U.S. market in 2021.

November 5, 2020 Press Release and Earnings Call

84. On November 5, 2020, the Company issued a press release announcing its third quarter 2020 financial results. In the press release, Defendant Palmer touted the completion of the rolling submission of the BLA for teplizumab and also indicated that the Company was "focused on preparing for a potential product approval and launch in mid-2021," stating, in relevant part:

> We are excited about the progress the Provention Bio team has made in recent months as we work to ***redefine the treatment landscape for T1D and other***

> ***autoimmune diseases***[.] Earlier this week, we announced our achievement of a major milestone with the completion of the rolling BLA submission for teplizumab for the delay or prevention of clinical T1D in at-risk individuals. ***In parallel with our regulatory efforts, we are focused on preparing for a potential product approval and launch in mid-2021.*** We recently introduced two national campaigns to educate key stakeholders about early-stage T1D and the potential advantages of screening populations at risk of developing clinical-stage disease.

(Emphasis added.)

85. Also on November 5, 2020, the Company held an earnings call in which it further discussed the Company's third quarter 2020 results (the "Q3 2020 Earnings Call") with investors and analysts. On the call, Defendant Palmer discussed the Company's plan regarding teplizumab in the following terms:

> We continue to be driven by the possibility of bringing the first disease modifying therapy for T1D to market and look forward to continuing to work with the FDA during the regulatory process. ***Throughout the remainder of 2020, we plan to transition and transform our company into a commercialization ready organization in anticipation of the potential launch of teplizumab next year.*** In addition to teplizumab our pipeline is rich with potential opportunities to fundamentally address the unmet needs associated with other serious autoimmune diseases. And we are passionate about advancing our therapeutic candidates to help both patients and their caregivers.

(Emphasis added.)

January 4, 2021 Press Release

86. On January 4, 2021, the Company issued a press release announcing that the FDA had filed the BLA for teplizumab. The press release also stated that the Company's request for Priority Review had been granted by the FDA, which set forth a user fee goal date of July 2, 2021. In the press release, Defendant Palmer touted the filing of the BLA for teplizumab as follows:

> The FDA's acceptance of our BLA represents a significant achievement for Provention Bio in our mission to deliver the first potential disease-modifying T1D therapy and drive a paradigm shift in how individuals at risk of developing the disease are treated . . . . We intend to work closely with the FDA to support their review while also ***preparing for a potential product launch in the third quarter of 2021.***

(Emphasis added.)

February 25, 2021 Annual Report, Press Release, and Conference Call

87. On February 25, 2021, the Company filed its annual report for the fiscal year ended December 31, 2020 with the SEC on Form 10-K (the "2020 10-K"). It was signed by each of the Individual Defendants and contained certifications signed by Defendants Palmer and Drechsler pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act and the Sarbanes-Oxley Act of 2002 ("SOX") attesting to the accuracy of the 2020 10-K, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors. The 2020 10-K made the following claims regarding the PK/PD Study:

> The FDA has confirmed that it will require the BLA for teplizumab to include analytical data demonstrating the comparability between the study drug previously manufactured by MacroGenics and Eli Lilly and the to-be-commercialized drug product derived from the drug substance manufactured by our contract manufacturing partner, AGC Biologics. In addition to conducting analytical tests to evaluate comparability, we have also conducted a double-blind, single low-dose, PK/ PD bridging study in healthy subjects to support the switch to teplizumab study drug derived from drug substance manufactured by AGC Biologics in our Phase 3 PROTECT study. This single low-dose study was the first time the teplizumab drug product derived from the drug substance manufactured by AGC Biologics has been used in humans. ***We believe, based on the data and our analysis, that the results of the PK/PD study suggest that the drug substances manufactured by AGC Biologics and Eli Lilly are comparable.***

(Emphasis added.)

88. That same day, February 25, 2021, the Company issued a press release reporting the financial results for the Company's "fourth quarter and full year ended December 31, 2020." In the press release, Defendant Palmer touted the Company's timeline for commercializing teplizumab, stating, in relevant part:

> ***2020 was a pivotal year for Provention Bio and the type 1 diabetes (T1D) landscape***[.] The FDA's filing of our BLA for teplizumab represents a momentous achievement for Provention Bio in ***our mission to potentially deliver the first***

> ***disease-modifying T1D therapy, which may catalyze a paradigm shift in how pre-symptomatic, at-risk patients are screened and treated before the clinical diagnosis of T1D.*** We look forward to working closely with the FDA to support the Agency's Priority Review, while ***we prepare for a potential commercial launch in the second half of this year.***

(Emphasis added.)

89. Under the section, "Fourth Quarter 2020 and Recent Corporate Highlights," the February 25, 2021 press release further stated, in relevant part:

> **FDA Filing of a BLA and Priority Review for Teplizumab for the Delay or Prevention of Clinical Type 1 Diabetes in At-risk Individuals**
>
> In January, Provention announced that the Biologics License Application (BLA) for teplizumab for the delay or prevention of clinical type 1 diabetes (T1D) in at-risk individuals has been filed by the FDA. The FDA also granted Provention's request for Priority Review and assigned a user fee goal date of July 2, 2021, under the Prescription Drug User-Fee Act (PDUFA). In its acceptance letter, the FDA stated that it is currently planning to hold an advisory committee meeting, tentatively scheduled for May 27, 2021. If approved, teplizumab will be the first disease-modifying therapy for T1D.
>
> Provention is currently also evaluating teplizumab in patients with newly diagnosed insulin-dependent T1D, the Phase 3 PROTECT study, and expects full enrollment of the study in the second half of this year.

90. Als on February 25, 2021, the Company held an earnings call in which it discussed the Company's financial results for the fourth quarter and fiscal year ended December 31, 2020 (the "Q4 2020 Earnings Call"). On the call, Defendant Palmer discussed teplizumab in the following terms:

> ***The momentum we accelerated throughout 2020 continues to be driven forward into 2021.*** As we announced at the beginning of last month, the FDA s filing of our biologics license application for teplizumab in our lead Type 1 diabetes at risk indication and this BLA is currently undergoing priority review by the agency with a PDUFA date of July 2, 2021.
>
> * * *
>
> The second regulatory consideration I would like to address pertains to comparability between drug product previously produced from Eli Lilly drug

> substance and that produced from our current manufacturing partner, AGC Biologics. ***We believe our assessment of the physiochemical analysis of the two drug products, which we submitted to the FDA in our CMC module, demonstrates these drug products to be comparable. This assessment is also supported by the comparability in PD parameters, evaluated in the PK/PD bridging study we conducted in healthy volunteers last year.***
>
> However, the single administration low dose study, also showed a slightly lower than target PK area under the curve for the AGC product, indicating that in that particular study, the AGC product may have cleared faster from the blood stream than the Lilly product. Based on our understanding of the relevant data and the extensive modeling, we have conducted to date, we do not believe this observation will have a clinically relevant impact on either the safety or efficacy of the AGC product.
>
> As many of you know, we had our BLA mid-cycle review meeting earlier this month. And we had an opportunity to discuss this topic for the first time with the FDA and share our points of view, regarding the interpretation of the data we have submitted. The FDA is still evaluating the PK/PD bridging study and we'll be conducting its own PK modeling to validate our conclusion.
>
> As a result of our Breakthrough Therapy designation for the at-risk indication, we continue to enjoy the benefit of frequent constructive and valuable dialogue with the agency on all aspects of our BLA filing and the preparations for our advisory committee meeting in May. ***Considering that teplizumab potentially represents the first disease-modifying therapeutic advance for T1D in over a century and given the substantial unmet need that remains for these patients and their families, we look forward to continuing to support the agency in its review of our BLA to be able to bring this innovative breakthrough therapy to patients later this year.***

(Emphasis added.)

91. On the same earnings call, in response to a question regarding the comparability between the drug product manufactured by AGC Biologics and being prepared for commercialization and the drug product originating from drug substance manufactured by Eli Lilly that was evaluated by the TN-10 study submitted in the BLA for teplizumab, Defendant Palmer stated, in relevant part:

> [W]hat we're dealing with in terms of the comparability is a very comprehensive panel of physiochemical analyses that release the product from the manufacturer side within specification and from a validated process now at AGC Biologics and

comparing that to the specification with regard to the Lilly substance manufactured a decade ago.

And in that context the products are comparable. That is our assessment. That is our belief and we believe that the agency will see that also. We then had a situation as you may recall where we started the PROTECT study with Lilly manufactured product and obviously have to transition to the AGC Biologics product. And we did as a single-dose study in healthy volunteers at a low dose because we obviously couldn't administer a full 14-day therapeutic dose to healthy individuals.

And we wanted to bridge to the new material in our PROTECT study. As a result of that single dose PK/PD bridging study again all of the parameters were within anticipated target especially the PD parameters which are more indicative of the efficacy and the safety with the exception of this AUC PK area under the curve. And that the AGC Biologics fell slightly below the target indicating that it cleared a little faster.

So, what we have done in evaluating internally and in the submissions we've made to the agency is very extensive modeling which is very typical in the industry to show what the consequence of that would be how the two products behave when you take into account 14 days at therapeutic dose?

And from that analysis from that modeling, we do not believe that the difference in area under the curve will result in a clinically relevant difference in the safety and the efficacy of teplizumab. And so that we've submitted to the agency the mid-cycle review meeting we had was the very first and only time to date that we've had to discuss that. We laid out our results our interpretation.

And obviously they were not going to make a decision at that meeting and they have indicated to us they will do their own modeling and we anticipate that they will make information requests in the coming week -- in the coming weeks in order to enable them to do a comparison between their modeling and our modeling and whether they arrive at the same conclusion that we do. ***And we are confident in the interpretation that we have submitted to them.***

(Emphasis added.)

March 3, 2021 Press Release

92. On March 3, 2021, the Company issued a press release titled "Provention Bio Announces Publication of Extended Follow-up Data from the Pivotal 'At-Risk' TN-10 Study of Teplizumab in Science Translational Medicine." In the press release, Defendant Palmer touted the Company's teplizumab timeline as follows:

> These data embolden our enthusiasm surrounding the potential impact teplizumab may have on the lives of T1D patients, families and caregivers[.] Outcomes such as these validate Provention's mission to intercept and prevent debilitating and life-threatening diseases. We continue working closely with the FDA in their review of our BLA submission for teplizumab. The PDUFA goal date is July 2, 2021.

93. The statements referenced in ¶¶ 82–92 herein were materially false and misleading and failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants failed to disclose, *inter alia*, that: (1) the BLA for teplizumab contained deficiencies and inadequacies that would preclude FDA approval of the BLA in its submitted form; (2) the supporting evidence for the BLA for teplizumab was weak; (3) therefore the approval prospects of the BLA for teplizumab and teplizumab's commercialization timeline had been overstated; and (4) the Company failed to maintain internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

March 29, 2021 Proxy Statement

94. On March 29, 2021, the Company filed the 2021 Proxy Statement on Schedule 14A with the SEC. Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski solicited the 2021 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.[1]

95. The 2021 Proxy Statement called for Company shareholders to, *inter alia*: (1) re-elect Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski to the Board;

[1] Plaintiff's allegations with respect to the misleading statements in the 2021 Proxy Statement are based solely on negligence; they are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants, and they do not allege, and do not sound in, fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these allegations and related claims.

(2) approve, on a non-binding advisory basis, the compensation of named executive officers; (3) approve, on a non-binding advisory basis, the frequency of future non-binding advisory votes on the compensation of named executive officers; (4) approve an amendment to the Second Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 100,000,000 to 150,000,000 shares; and (5) ratify the appointment of EisnerAmper LLP as the Company's independent registered public accounting firm for the year ending December 31, 2021.

96. The 2021 Proxy Statement also detailed the principal functions of the Audit Committee, which at that time consisted of Defendants Catlin, Doherty, and Pisano. These functions included the following:

> The Board has established an Audit Committee currently consisting of Mr. Catlin (Chair), Mr. Doherty and Mr. Pisano. The Audit Committee's primary functions are to oversee and review the integrity of the Company's financial statements and other financial information furnished by us, our compliance with legal and regulatory requirements, our systems of internal accounting and financial controls, our independent auditor's engagement, qualifications, performance, compensation and independence, related party transactions, and compliance with our Code of Business Conduct and Ethics.
>
> The Audit Committee also appoints (and recommends that the Board submit for shareholder ratification), compensates, retains and oversees the independent auditor retained for the purpose of preparing or issuing an audit report or other related service. The Audit Committee pre-approves audit, review and non-audit services provided by our independent auditor pursuant to the pre-approval policy described in additional detail herein. In addition, the Audit Committee discusses guidelines and policies related to risk assessment and risk management with us, prepares an Audit Committee report in accordance with SEC regulations, sets policies regarding the hiring of employees or former employees of our independent auditor, reviews and investigates any matters pertaining to integrity of management, including conflicts of interest, reviews related party transactions, reviews financial reporting and accounting standards, meets with officers as necessary, reviews the independence of the independent public accountants and reviews the adequacy of our internal accounting controls.
>
> Each member of the Audit Committee is "independent" as that term is defined under the applicable rules of the SEC and Nasdaq. The Board has determined that

> each Audit Committee member has sufficient knowledge in financial and auditing matters to serve on the Committee. The Board determined that Mr. Catlin is an "audit committee financial expert," as defined under the applicable rules of the SEC. The Audit Committee met five times during 2020. Our Board has adopted an Audit Committee Charter, which is available for viewing at www.proventionbio.com.

97. Under the section, "Proposal No. 5," the 2021 Proxy Statement stated, in relevant part:

> The Audit Committee is responsible for reviewing and discussing the audited financial statements with management, discussing with the independent registered public accountants the matters required by Public Company Accounting Oversight Board Auditing Standard No. 1301 Communications with Audit Committees, receiving written disclosures from our independent registered public accounting firm required by the applicable requirements of the Public Company Accounting Oversight Board regarding the independent registered public accountants' communications with the Audit Committee concerning independence and discussing with the independent registered public accountants their independence, and recommending to the Board that the audited financial statements be included in our Annual Report on Form 10-K.

98. Under the heading "Code of Business Conduct and Ethics," the 2021 Proxy Statement stated, in relevant part:

> We have adopted a Code of Business Conduct and Ethics that applies to our directors, officers and employees. The purpose of the Code of Business Conduct and Ethics is to deter wrongdoing and to provide guidance to directors, officers and employees to help them recognize and deal with ethical issues, to provide mechanisms to report unethical or illegal conduct and to contribute positively to our culture of accurate disclosure, ethical performance and accountability.

99. Additionally, under the heading "Board Role in Risk Oversight," the 2021 Proxy Statement stated the following:

> Our Board has primary responsibility for the oversight of material risks facing the Company. We face a number of risks, including those described under the section entitled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and other reports filed with the SEC. We are committed to promoting a culture of decision-making that is risk-adjusted, taking into account material risks without hindering innovation. We believe that successful risk management requires understanding the risks we face, monitoring them, and adopting appropriate mitigation measures. To that end, our Board receives regular

> reports directly from officers responsible for oversight of particular risks within our Company, as well as full reports from each committee chair regarding the committee's considerations and actions with regard to risks facing the Company (as described below).Through these reports and other discussions with management and Board committees, our Board monitors management's performance of its responsibilities to identify relevant risks and assess, monitor, and take appropriate steps to mitigate risks.
>
> We are committed to corporate social responsibility, including environmental sustainability, diversity and inclusion. Our Board takes its role in overseeing corporate social responsibility seriously and believes that good corporate governance and high ethical standards are key to our Company's future success.
>
> At the committee level, our Audit Committee discusses guidelines and policies developed by our management and the Board with respect to risk assessment and risk management and the steps that our management has taken to monitor and control financial risk exposure, including anti-fraud programs and controls. In addition, our Audit Committee has established procedures for the receipt, retention and treatment of complaints regarding various matters, including the confidential submission by employees of concerns relating to questionable accounting or auditing matters or violations of our Code of Business Conducts and Ethics. The Compensation Committee considers, and reviews and discusses narrative disclosure of, the relation of the Company's compensation policies and practices to compensation risk and risk management. Our Nominating and Corporate Governance Committee considers and makes recommendations pertaining to the Board's leadership structure. As described above, our leadership structure currently reflects our belief in the value of promoting the role of independent directors in risk management.

100. Under the heading "Organizational Growth and Financings," the 2021 Proxy Statement further stated, in relevant part:

> Since January 2020, we successfully raised approximately $215.5 million from our at-the-market program and a public offering, including approximately $113.2 million in 2020, ***to fund the company's advancement of its pipeline of product candidates and other operations, including our activities to prepare for a potential commercialization of teplizumab.***

(Emphasis added.)

101. The above statements in the 2021 Proxy Statement were false and misleading because they failed to disclose, *inter alia*, that: (1) contrary to the 2021 Proxy Statement's descriptions of the Board's risk oversight function and the Audit Committee's responsibilities, the

Board and the Audit Committee were not adequately exercising these functions and were causing or permitting the Company to issue false and misleading statements; and (2) the Individual Defendants on the Board at that time who were breaching their fiduciary duties were improperly seeking shareholder approval of their re-election to the Board so as to entrench themselves on the Board and continue their misconduct and breach of their fiduciary duties.

102. Moreover, the 2021 Proxy Statement was false and misleading because it also failed to disclose, *inter alia*, that: (1) the BLA for teplizumab contained deficiencies and inadequacies that would preclude FDA approval of the BLA in its submitted form; (2) the supporting evidence for the BLA for teplizumab was weak; (3) therefore the approval prospects of the BLA for teplizumab and teplizumab's commercialization timeline had been overstated; and (4) the Company failed to maintain internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

103. As a result of the material misstatements and omissions contained in the 2021 Proxy Statement, Company shareholders, among other things: (1) re-elected Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski to the Board, which allowed them to breach their fiduciary duties to the Company and (2) approved the compensation of named executive officers, allowing Defendants Palmer and Drechsler to improperly increase their unjust compensation to the detriment of the Company.

The Truth Emerges

April 8, 2021 Press Release

104. On April 8, 2021, the Company issued a press release providing a regulatory update on the BLA for teplizumab. The press release disclosed, in relevant part:

> [T]he Company received a notification on April 2, 2021 from the U.S. Food and Drug Administration (FDA), stating that, as part of its ongoing review of the

> Company's Biologic License Application (BLA) for teplizumab for the delay or prevention of clinical type 1 diabetes, ***the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time.*** The FDA stated in the correspondence that the notification does not reflect a final decision on the information under review.
>
> Additionally, during an informal discussion on April 2, 2021 regarding the agenda for the upcoming Advisory Committee meeting scheduled for May 27, 2021, ***the FDA informed the Company that it had completed its review of the data and analysis submitted by the Company for its single, low-dose pharmacokinetic/pharmacodynamic (PK/PD) bridging study conducted in healthy volunteers. This study evaluated the PK/PD comparability of drug product originating from drug substance manufactured by AGC Biologics, which the Company plans to use for commercialization, and drug product originating from historic drug substance manufactured by Eli Lilly used for the TN-10 study submitted for the teplizumab BLA. The FDA indicated that based on the data it has reviewed to date, the Agency's position is that the PK profiles of the two drug products evaluated in the PK/PD bridging study were not comparable*** and that additional data would be required before the FDA's considerations could be satisfied. As a follow up, today, the FDA stated to the Company that it is willing to discuss these issues concurrently with its ongoing review.

(Emphasis added.)

105. On this news, Provention's share price dropped $1.73 (or 17.8%) to close at $8.00 on April 9, 2021.

Subsequent Events and Disclosures

April 27, 2021 Press Release

106. On April 27, 2021, the Company issued a press release announcing that the Company had taken part in an informal meeting with the FDA on April 23, 2021 in relation to the FDA's then-ongoing review of the BLA for teplizumab. According to the press release, the purpose of the April 23, 2021 meeting was "to discuss the FDA's considerations, thus far, regarding comparability between the Company's proposed commercial product and drug product used historically in clinical trials originating from drug substance manufactured by Eli Lilly over a decade ago." The press release further stated, in relevant part:

> The FDA reported at the meeting that it had concluded that the pharmacokinetic (PK) profiles of the two drug products evaluated in the Company's single, low-dose pharmacokinetic/pharmacodynamic (PK/PD) bridging study conducted in healthy volunteers are not comparable, since the intended commercial product did not meet the pre-specified 80-125% PK area under the curve (AUC) comparability target range. The FDA also stated that it cannot be certain if this observation is not clinically relevant, given that the relationship between transient lymphocyte reduction, a PD marker, which was comparable in the PK/PD bridging study, and clinical efficacy, has yet to be fully validated.

107. The April 27, 2021 press release also stated that the FDA recommended that "both the FDA and the Company update their Advisory Committee briefing materials to reflect the removal of the term 'prevention' from the previously proposed indication, as the remaining term 'delay' more accurately reflects the results of the TN-10 trial."

July 6, 2021 Press Release

108. On July 6, 2021, the Company issued a press release entitled "Provention Bio Receives Complete Response Letter (CRL) to Biologics License Application (BLA) for Teplizumab for the Delay of Clinical Type 1 Diabetes (T1D) in At-risk Individuals," announcing that the FDA determined the BLA for teplizumab to be inadequate for approval. The press release stated, in relevant part:

> In the CRL, received late evening on July 2nd, 2021, the FDA stated that a single, low-dose pharmacokinetic/pharmacodynamic (PK/PD) bridging study in healthy volunteers to compare planned commercial product with drug product originating from drug substance manufactured for historic clinical trials had failed to show PK comparability. "As PK remains the primary endpoint for demonstration of comparability between the two products, you will need to establish PK comparability appropriately between the intended commercial product and the clinical trial product or provide other data that adequately justify why PK comparability is not necessary."
>
> The Company expects relevant additional PK/PD data being, or to be, collected from a PK/PD substudy in patients receiving 12-days of therapy in the ongoing Phase 3 PROTECT trial in newly diagnosed T1D patients later this quarter. These data will be analyzed by independent, unblinded third-parties to maintain the integrity of this placebo-controlled trial. Upon review of the results from this substudy, the Company will determine whether to submit these data to the FDA for

> its review, along with any other relevant data and analyses based on our ongoing discussions with FDA, to support PK comparability or otherwise justify why PK comparability is not necessary.
>
> In the CRL, the FDA cited several additional considerations related to product quality, which the Company believes have either been addressed in amendments already submitted to the BLA or can be addressed in the short-term. The CRL acknowledged that the FDA had not reviewed several amendments already submitted by the Company in response to certain Chemistry, Manufacturing and Controls (CMC) information requests.
>
> The FDA also stated that certain deficiencies conveyed during a recent general inspection, not specific to teplizumab, at a fill/finish manufacturing facility used by the Company will need to be resolved before approval.

109. On this news, Provention's share price plunged $2.19 (or 26.4%) from $8.30 at close on July 2, 2021 to $6.11 at close on July 6, 2021, the next trading day.

DAMAGES TO PROVENTION

110. As a direct and proximate result of the Individual Defendants' conduct, Provention has lost and expended, and will lose and expend, many millions of dollars.

111. Such expenditures include, but are not limited to, legal fees associated with the Securities Class Action filed against the Company and certain of its current and former officers and directors, any governmental investigations, any internal investigations, and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

112. Such losses include, but are not limited to, handsome compensation and benefits paid to the Individual Defendants who breached their fiduciary duties to the Company.

113. As a direct and proximate result of the Individual Defendants' conduct, Provention has also suffered and will continue to suffer a loss of reputation and goodwill, and a "liar's discount" that will plague the Company's stock in the future due to the Company's and their misrepresentations and the Individual Defendants' breaches of fiduciary duties and unjust enrichment and other violations of law.

DERIVATIVE ALLEGATIONS

114. Plaintiff brings this action derivatively and for the benefit of Provention to redress injuries suffered, and to be suffered, as a result of the Individual Defendants' breaches of their fiduciary duties as directors and/or officers of Provention, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violations of the Exchange Act, as well as the aiding and abetting thereof.

115. Provention is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

116. Plaintiff is, and has continuously been at all relevant times, a shareholder of Provention. Plaintiff will adequately and fairly represent the interests of Provention in enforcing and prosecuting its rights, and, to that end, has retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

DEMAND FUTILITY ALLEGATIONS

117. Plaintiff incorporates by reference and realleges each and every allegation stated above as if fully set forth herein.

118. A pre-suit demand on the Board of Provention is futile and, therefore, excused. At the time of filing of this action, the Board consists of the following seven individuals: Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski (the "Directors"). Plaintiff needs only to allege demand futility as to four of these seven Directors.

119. Demand is excused as to all of the Directors because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of the schemes they engaged in knowingly or recklessly to make and/or cause the Company to make false and misleading statements and omissions of material fact, all of which renders the Directors unable to

impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

120. In complete abdication of their fiduciary duties, the Directors either knowingly or recklessly participated in making and/or causing the Company to make the materially false and misleading statements alleged herein. The fraudulent scheme was, *inter alia*, intended to make the Company appear more profitable and attractive to investors. As a result of the foregoing, the Directors breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

121. Additional reasons that demand on Defendant Palmer is futile follow. Defendant Palmer has served as Provention's President and CEO and as a Company director since 2016. Thus, as the Company admits, he is a non-independent director. The Company provides Defendant Palmer with his principal occupation for which he receives handsome compensation as detailed above. As CEO, Defendant Palmer was ultimately responsible for the many false and misleading statements and omissions that were made, including those contained in the Company's press releases, the 2020 10-K, which he personally signed and signed SOX certifications for, and the 2021 Proxy Statement, which was solicited on his behalf and led to his re-election to the Board, allowing him to continue breaching his fiduciary duties to the Company. As the Company's highest officer and as a trusted Company director, he conducted little, if any, oversight of the scheme to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Palmer is a defendant in the Securities Class Action. For these reasons, Defendant Palmer breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore,

excused.

122. Additional reasons that demand on Defendant Bluestone is futile follow. Defendant Bluestone has served as a Company director since March 2019. He has received and continues to receive substantial compensation for his role as a director as described above. As a trusted Company director, Defendant Bluestone conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Furthermore, Defendant Bluestone signed, and thus personally made the false and misleading statements in the 2020 10-K; the 2021 Proxy Statement, which also contained false and misleading statements, was solicited on his behalf and led to his re-election to the Board, allowing him to continue breaching his fiduciary duties. For these reasons, Defendant Bluestone breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterred, and thus demand upon him is futile and, therefore, excused.

123. Additional reasons that demand on Defendant Catlin is futile follow. Defendant Catlin has served as a Company director since September 2018. He also serves as the Chair of the Audit Committee and as a member of the Compensation Committee. Defendant Catlin has received and continues to receive substantial compensation for his role as a director as described above. As a trusted Company director, Defendant Catlin conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Furthermore, Defendant Catlin signed, and thus personally made the false and misleading statements in the 2020 10-K; the 2021 Proxy Statement, which also contained false and misleading statements, was solicited on his behalf and led to his re-

election to the Board, allowing him to continue breaching his fiduciary duties. For these reasons, Defendant Catlin breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

124. Additional reasons that demand on Defendant Doherty is futile follow. Defendant Doherty has served as a Company director since September 2019. He also serves as a member of the Audit Committee and as a member of the Nominating and Corporate Governance Committee. Defendant Doherty has received and continues to receive substantial compensation for his role as a director as described above. As a trusted Company director, Defendant Doherty conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Furthermore, Defendant Doherty signed, and thus personally made the false and misleading statements in the 2020 10-K; the 2021 Proxy Statement, which also contained false and misleading statements, was solicited on his behalf and led to his re-election to the Board, allowing him to continue breaching his fiduciary duties. For these reasons, Defendant Doherty breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

125. Additional reasons that demand on Defendant Jenkins is futile follow. Defendant Jenkins has served as a Company director since August 2020. He also serves as a member of the Nominating and Corporate Governance Committee. Defendant Jenkins has received and continues to receive substantial compensation for his role as a director as described above. As a trusted Company director, Defendant Jenkins conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor

such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Furthermore, Defendant Jenkins signed, and thus personally made the false and misleading statements in the 2020 10-K; the 2021 Proxy Statement, which also contained false and misleading statements, was solicited on his behalf and led to his re-election to the Board, allowing him to continue breaching his fiduciary duties. For these reasons, Defendant Jenkins breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

126. Additional reasons that demand on Defendant Pisano is futile follow. Defendant Pisano currently serves as Chairman of the Board and has served as a Company director since April 2018. He also serves as the Chair of the Nominating and Corporate Governance Committee, as a member of the Audit Committee, and as a member of the Compensation Committee. Defendant Pisano has received and continues to receive substantial compensation for his role as a director as described above. As a trusted Company director, Defendant Pisano conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Furthermore, Defendant Pisano signed, and thus personally made the false and misleading statements in the 2020 10-K; the 2021 Proxy Statement, which also contained false and misleading statements, was solicited on his behalf and led to his re-election to the Board, allowing him to continue breaching his fiduciary duties. For these reasons, Defendant Pisano breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

127. Additional reasons that demand on Defendant Wysenski is futile follow. Defendant

Wysenski has served as a Company director since May 2020. She also serves as the Chair of the Compensation Committee and as a member of the Nominating and Corporate Governance Committee. Defendant Wysenski has received and continues to receive substantial compensation for her role as a director as described above. As a trusted Company director, Defendant Wysenski conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded her duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded her duties to protect corporate assets. Furthermore, Defendant Wysenski signed, and thus personally made the false and misleading statements in the 2020 10-K; the 2021 Proxy Statement, which also contained false and misleading statements, was solicited on her behalf and led to her re-election to the Board, allowing her to continue breaching her fiduciary duties. For these reasons, Defendant Wysenski breached her fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon her is futile and, therefore, excused.

128. Defendants Catlin, Doherty, and Pisano (the "Audit Committee Defendants") served as members of the Audit Committee. Pursuant to the Company's Audit Committee Charter, the Audit Committee Defendants are responsible for overseeing, among other things, the integrity of the Company's financial statements, the Company's accounting and financial reporting processes and financial statement audits, the Company's systems of internal control over financial reporting and disclosure controls and procedures, and the Company's compliance with legal and regulatory requirements. The Audit Committee Defendants failed to fulfill these obligations, as they are charged to do under the Audit Committee Charter, allowing the Company to issue materially false and misleading statements to the public during the Relevant Period and to fail to maintain internal controls. Thus, the Audit Committee Defendants breached their fiduciary duties,

are not disinterested, and demand is excused as to them.

129. The Directors have longstanding business and personal relationships with each other and the Individual Defendants that preclude them from acting independently and in the best interests of the Company and the shareholders. For instance, Defendants Catlin and Jenkins have concurrently served on the board of directors of Corbus Pharmaceuticals Holdings, Inc. since 2018. Furthermore, Defendant Drechsler and Defendant Pisano had overlapping tenures at VaxInnate Corporation, where Defendant Drechsler served as CFO and Defendant Pisano served as President and CEO. These conflicts of interest precluded the Directors from adequately monitoring the Company's operations and internal controls and calling into question the Individual Defendants' conduct. Thus, the Directors face a substantial likelihood of liability and demand is futile as to them.

130. In violation of the Code of Conduct and the Audit Committee Charter, the Directors conducted little, if any, oversight of the Company's internal controls over public reporting, and of the Company's engagement in the Individual Defendants' scheme to issue materially false and misleading statements to the public and facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, gross mismanagement, abuse of control, waste of corporate assets, violations of the Exchange Act, and the claims alleged in the Securities Class Action. In violation of the Code of Conduct and the Audit Committee Charter, the Directors failed to comply with laws and regulations, maintain the accuracy of company records, public reports and communications, and uphold the responsibilities related thereto. Thus, the Directors face a substantial likelihood of liability and demand is futile as to them.

131. Provention has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Directors have not filed any lawsuits against themselves

or others who were responsible for that wrongful conduct to attempt to recover for Provention any part of the damages Provention suffered and will continue to suffer thereby. Thus, any demand upon the Directors would be futile.

132. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Directors can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

133. The acts complained of herein constitute violations of fiduciary duties owed by Provention officers and directors, and these acts are incapable of ratification.

134. The Directors may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Provention. If there is a directors' and officers' liability insurance policy covering the Directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Directors, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Directors were to sue themselves or certain of the officers of Provention, there would be no directors' and officers' insurance protection. Accordingly, the Directors cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance

policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Directors is futile and, therefore, excused.

135. If there is no directors' and officers' liability insurance, then the Directors will not cause Provention to sue the Individual Defendants named herein, since, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

136. Thus, for all of the reasons set forth above, all of the Directors, and, if not all of them, at least four of the Directors, cannot consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

FIRST CLAIM

Against Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski for Violations of Section 14(a) of the Exchange Act

137. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

138. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that "[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l]."

139. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false

or misleading." 17 C.F.R. § 240.14a-9.

140. Under the direction and watch of the Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski, the 2021 Proxy Statement failed to disclose, *inter alia*: (1) contrary to the 2021 Proxy Statement's descriptions of the Board's risk oversight function and the Audit Committee's responsibilities, the Board and the Audit Committee were not adequately exercising these functions and were causing or permitting the Company to issue false and misleading statements; and (2) the Individual Defendants on the Board at that time who were breaching their fiduciary duties were improperly seeking shareholder approval of their re-election to the Board so as to entrench themselves on the Board and continue the Individual Defendants' misconduct and breach of their fiduciary duties.

141. Furthermore, under the direction of the Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski, the 2021 Proxy Statement failed to disclose, *inter alia*: (1) the BLA for teplizumab contained deficiencies and inadequacies that would preclude FDA approval of the BLA in its submitted form; (2) the supporting evidence for the BLA for teplizumab was weaker than investors had been led by the Company to believe; (3) the Company therefore had exaggerated the approval prospects of the BLA for teplizumab as well as teplizumab's commercialization timeline; and (4) the Company failed to maintain internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

142. In the exercise of reasonable care, the Directors should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2021 Proxy Statement were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the

Proxy Statement, including, but not limited to, approval of the compensation of named executive officers, allowing certain of the Individual Defendants to receive further unjust compensation.

143. The false and misleading elements of the Proxy Statement also led to, *inter alia*, the re-election of Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski, which allowed them to continue breaching their fiduciary duties to the Company.

144. The Company was damaged as a result of Defendants Palmer, Bluestone, Catlin, Doherty, Jenkins, Pisano, and Wysenski's material misrepresentations and omissions in the Proxy Statement.

145. Plaintiff on behalf of Provention has no adequate remedy at law.

SECOND CLAIM

Against Individual Defendants for Breach of Fiduciary Duties

146. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

147. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Provention's business and affairs.

148. Each of the Individual Defendants violated and breached his or her fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

149. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Provention.

150. In breach of their fiduciary duties owed to Provention, the Individual Defendants also willfully or recklessly made and/or caused the Company to make false and misleading

statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) the BLA for teplizumab contained deficiencies and inadequacies that would preclude FDA approval of the BLA in its submitted form; (2) the supporting evidence for the BLA for teplizumab was weak; (3) therefore the approval prospects of the BLA for teplizumab and teplizumab's commercialization timeline had been overstated; and (4) the Company failed to maintain internal controls . As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

151. The Individual Defendants failed to correct and/or caused the Company to fail to rectify any of the wrongs described herein or correct the false and misleading statements and omissions of material fact referenced herein, rendering them personally liable to the Company for breaching their fiduciary duties.

152. In further breach of their fiduciary duties, the Individual Defendants failed to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls.

153. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent scheme set forth herein and to fail to maintain adequate internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent scheme and to fail to maintain adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of the Company's securities. The Individual Defendants, in good faith, should have taken appropriate

action to correct the schemes alleged herein and to prevent them from continuing to occur.

154. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

155. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Provention has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

156. Plaintiff on behalf of Provention has no adequate remedy at law.

THIRD CLAIM

Against Individual Defendants for Unjust Enrichment

157. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

158. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Provention.

159. The Individual Defendants either benefited financially from the improper conduct or received unjustly lucrative bonuses tied to the false and misleading statements, or received bonuses, stock options, or similar compensation from Provention that was tied to the performance or artificially inflated valuation of Provention, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

160. Plaintiff, as a shareholder and a representative of Provention, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits—including from benefits and other compensation, including any performance-based or valuation-based compensation—obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary duties.

161. Plaintiff on behalf of Provention has no adequate remedy at law.

FOURTH CLAIM

Against the Individual Defendants for Abuse of Control

162. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

163. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Provention, for which they are legally responsible.

164. As a direct and proximate result of the Individual Defendants' abuse of control, Provention has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

165. Plaintiff on behalf of Provention has no adequate remedy at law.

FIFTH CLAIM

Against the Individual Defendants for Gross Mismanagement

166. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

167. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Provention in a manner consistent with the operations of a publicly-held corporation.

168. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Provention has sustained and will continue to sustain significant damages.

169. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

170. Plaintiff on behalf of Provention has no adequate remedy at law.

SIXTH CLAIM

Against Individual Defendants for Waste of Corporate Assets

171. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

172. As a result of the foregoing, and by failing to properly consider the interests of the Company and its public shareholders, Defendants have caused Provention to waste valuable corporate assets, to incur many millions of dollars of legal liability and costs to defend unlawful actions, and to lose financing from investors and business from future customers who no longer trust the Company and its products.

173. As a result of the waste of corporate assets, the Individual Defendants are each liable to the Company.

174. Plaintiff on behalf of Provention has no adequate remedy at law.

SEVENTH CLAIM

Against Defendants Palmer and Drechsler for Contribution Under Sections 10(b) and 21D of the Exchange Act

175. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

176. Provention and Defendants Palmer and Drechsler are each named as defendants in the Securities Class Action, which asserts claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, as well as Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Action for these violations of the federal securities laws, the Company's liability will be in whole or in part due to Defendants

Palmer's and Drechsler's willful and/or reckless violations of their obligations as officers and/or directors of Provention.

177. Defendants Palmer and Drechsler, because of their positions of control and authority as officers and/or directors of Provention, were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of Provention, including the wrongful acts complained of herein and in the Securities Class Action.

178. Accordingly, Defendants Palmer and Drechsler are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

179. As such, Provention is entitled to receive all appropriate contribution or indemnification from Defendants Palmer and Drechsler.

PRAYER FOR RELIEF

180. FOR THESE REASONS, Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows:

(a) Declaring that Plaintiff may maintain this action on behalf of Provention, and that Plaintiff is an adequate representative of the Company;

(b) Declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Provention;

(c) Determining and awarding to Provention the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

(d) Directing Provention and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with

applicable laws and to protect Provention and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Certificate of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies:

1. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;

2. a provision to permit the shareholders of Provention to nominate at least four candidates for election to the Board; and

3. a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations.

(e) Awarding Provention restitution from the Individual Defendants, and each of them;

(f) Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

(g) Granting such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: August 5, 2021

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

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Counsel for Plaintiff

VERIFICATION

I, Sauro Liberatore a plaintiff in the within action. I have reviewed the allegations made in this verified consolidated shareholder derivative complaint, know the contents thereof, and authorize its filing. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct. Executed this _th day of 8/5/2021, 2021.

DocuSigned by:
1725588BC763423...

Sauro Liberatore